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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Michael S. Tyndall, et al. Art Unit 1616
Serial No. 10/633,945
Filed August 4, 2003
Confirmation No. 5207
For TOPICAL VETERINARY COMPOSITIONS AND METHODS FOR THE TREATMENT AND PREVENTION OF INFECTION
Examiner Lakia Tongue

July 6, 2005

RESPONSE TO RESTRICTION REQUIREMENT / ELECTION OF SPECIES

TO THE COMMISSIONER FOR PATENTS,

SIR/MADAM:

The Office has required election between Group I (claims 1 - 35) and Group II (claims 36 - 51). In this instance, the Group I claims are drawn to a topical veterinary composition for the treatment or prevention of infection in animals. The Group II claims are drawn to a method of treating/preventing animal infection, the method comprising topically applying a composition having the same elements as are recited in claim 1.

Reconsideration is respectfully requested of the restriction requirement and, in particular, of the reason stated in the Office action for the restriction requirement. The basis for the restriction requirement on page 2 of the Office action dated June 6, 2005 is the following assertion:

> The inventions are distinct if it can be shown that either: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product(MPEP 806.05(h)). In the instant case invention I can be used to impair the growth of nosocomial infection of humans.

This basis is incorrect. The Office asserts that invention I can be used to impair the growth of nosocomial infection of humans but offers no evidence to show this is true. Moreover, the composition of the Group I claims is specifically stated to

be "**a veterinary composition** for treatment or prevention of infection in **animals**." The Office, therefore, has not shown that the composition of the Group I claims could be used in a materially different process from that of claims 36-51. Accordingly, applicants request withdrawal of the restriction requirement because the basis therefore is incorrect.

The applicants' main claims 1 and 36 closely track one another:

> Claim 1: A topical veterinary composition for the treatment or prevention of infection in animals comprising an antimicrobial agent and a phospholipid-containing skin conditioner.
>
> Claim 36: A method to treat or prevent infection in an animal comprising topically applying to the animal a veterinary composition comprising an anti-microbial agent and a phospholipid-containing skin conditioner.

Withdrawal of the restriction requirement is therefore also requested on the basis of the following instruction from MPEP 803:

> "If the search and examination can be made without serious burden, the examiner must examine it on the merits, even if it includes claims to distinct or independent inventions." (emphasis added)

In this regard, applicants respectfully ask the Office to consider the relative burdens on the Office and the applicants, as well as the similar nature of these claims, as directed by MPEP 803. Claim 1 and claim 36 were intentionally drafted to closely mirror each other and to capture the same inventive concepts. In order for a reliable search to be conducted for either the applicants' composition or method claims, both Class/subclass combinations will have to be searched. Accordingly, maintaining all claims in the application should not add more than a minimal burden.

The applicants further emphasize that the Office often examines both composition and method claims in the same

application in situations such as this. Recently issued patents with claims directly analogous to applicants' claims include the following:

6,821,508

Composition and method for topical nail treatment

Claim 1: A composition comprising sulfur-containing glycine residues and urea which increases the permeation of an active agent through nail tissue.

Claim 2: A method of treating a nail disease comprising topically applying the composition of claim 1 in an amount sufficient to increase the permeation of an active agent through nail tissue.

6,518,246

Pharmaceutical composition and method for the treatment of neoplastic cells

Claim 1: A pharmaceutical composition effective for treating human or non-human neoplastic disorder, comprising pharmaceutically effective amounts of each of galanin, octreotide and serotonin, in admixture with a pharmaceutically acceptable carrier.

Claim 3: A method for treatment of neoplastic disorders in a human or non-human animal, comprising administering to such an animal in need of the same, a pharmaceutically effective amount of a pharmaceutical composition as claimed in claim 1.

6,395,728

Method of treatment and pharmaceutical composition

Claim 1: A method for the treatment or prevention of hypertension associated with diabetes comprising administering a therapeutically effective amount of a combination consisting essentially of (i) the AT_1-antagonist valsartan or a pharmaceutically acceptable salt thereof and (ii) the Calcium channel blocker amlodipine or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier to a mammal in need thereof.

Claim 2: A pharmaceutical combination composition consisting essentially of (i) the AT_1-antagonist valsartan or a pharmaceutically acceptable salt thereof and (ii) the Calcium channel blocker amlodipine or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier.

6,337,076

Method and composition for the treatment of scars

Claim 1: A method of treating hypertrophic scars so as to reduce the size and/or improve the appearance thereof comprises; applying onto a hypertrophic scar a liquid composition comprising a Collodion film-forming carrier having contained therein a dermatologically effective amount of an active ingredient capable of reducing the size of the scar or improving the appearance thereof, drying said film-forming carrier to form a dry protective film physically adhered to said scar to maintain contact of the active ingredients on said scar.

Claim 11: A composition for treating adverse skin conditions comprising a liquid Collodion film-forming carrier and a dermatologically effective amount of an active ingredient comprising a topically active steroid, silicone gel, vitamins or mixtures of said active ingredients, wherein said liquid carrier is capable of drying to a dry protective film physically adhered to skin and containing said active ingredient.

6,174,857

Composition and method for the treatment of osteoporosis in mammals

Claim 1: A pharmaceutical composition suitable for parenteral administration for the treatment or prevention of osteoporosis in a mammal comprising:

(a) Insulin-Like Growth Factor I (IGF-1) or an active fragment thereof, in an amount sufficient to prevent, slow, stop, or reverse the bone mineral density reduction rate in a mammal exhibiting bone mineral density reduction;

(b) a bone antiresorptive effective amount of a bone antiresorptive compound; and

(c) a pharmaceutically acceptable carrier.

Claim 10: A method for the treatment of osteoporosis in a mammal having reduced bone mineral density or prevention thereof in a mammal prone thereto comprising administering to said mammal a composition according to claim 2, in an amount sufficient to prevent, slow, stop, or reverse the bone mineral density reduction rate in said mammal.

6,224,896

Composition and process for the treatment of epidermal traumas such as decubitus ulcers

Claim 1: A composition for treating epidermal traumas, said composition formed in several adjacent layers applied onto a bandage or a patch comprising: a first wound-treating layer including a nitroimadazole compound; a second occlusive skin barrier layer including zinc oxide and a third occlusive synthetic dressing layer including aloe vera, said first layer being adjacent said second layer, said second layer being adjacent said third layer, and said third layer being applied onto a bandage or a patch.

Claim 7: A method of treating epidermal traumas comprising: cleaning a epidermal trauma;

drying said epidermal trauma;

soaking gauze pads in a nitroimadazole compound solution;

forming a first treatment layer in said epidermal trauma by placing the soaked pads into contact with said epidermal trauma;

forming a second treatment layer by circling the epidermal trauma with an occlusive skin barrier, said occlusive skin barrier including zinc oxide, said second treatment layer having said occlusive skin barrier being spaced from contact with said epidermal trauma;

placing an occlusive synthetic dressing of aloe vera on a dry gauze pad; and

forming a third treatment layer overlaying said first and second layers by placing said dry gauze pad over said epidermal trauma.

These are not isolated instances, as the patent collection is replete with such patents. While this is not controlling on the Office in the present case, applicants respectfully request that it be taken into account when weighing i) the relative burdens, ii) the closely parallel nature of applicants'

composition and method claims, and iii) the overlapping, if not identical, nature of the respective searches required.

The applicants respectfully submit that the burden of examining the additional claims having overlapping search fields cannot fairly be said to be "serious." In contrast, applicants would incur filing fees of about $1000, issue fees of about $1,400, and maintenance fees of about $8,000 or more if required to prosecute and maintain a second application/patent, such fees being in addition to the similar fees to be incurred in this first application. This financial burden is exacerbated by the fact that extra claim fees of $800 were paid in the present application.

In view of the foregoing, applicants respectfully ask the Office to withdraw the restriction requirement. Subject to the foregoing the claims of Group I (claims 1 - 35) are elected for examination in this application if the restriction requirement is not withdrawn.

Where an election of Group I is made, the Office has also required an election of a single species including one antimicrobial and one skin conditioner.

Reconsideration is requested concerning the election of a single compound. As stated above, restriction pursuant to 35 U.S.C. 121 is proper only upon a ***showing*** that two or more ***independent and distinct*** inventions are claimed in one application. The Office has made no such showing. Instead, the Office has merely asserted that the claims of Group I and II contain a plurality of patentably distinct compounds. This bare assertion is statutorily insufficient. Furthermore, "[i]f the search and examination of an entire application can be made **without serious burden**, the Examiner **must** examine it on the

merits, even though it includes claims to distinct or independent inventions."[1]

Accordingly, the Office's asserted basis for election of species is improper and the requirement should be withdrawn. Applicants elect the following components in the event the Office is not persuaded to withdraw this election requirement:

For the antimicrobial, applicants elect iodine.

For the skin conditioner, applicants elect alkyl.

For situations where three components are needed, applicants elect synthetic surfactant for the third component.

Claims 1 - 35 read on the species elected.

According to MPEP §809.02(c), an Examiner's action subsequent to an election of species should include a complete action on the merits of all claims readable on the elected species and according to MPEP §809.02(e), whenever a generic claim is found to be allowable in substance, action on the species claims shall thereupon be given as if the generic claim were allowed. Thus, if it is determined that the elected species is patentable, it is incumbent upon the Office to search additional species that fall within any allowable generic claims.

Applicants note that their process claims include all the limitations of their product claims. As stated in the Office action, therefore, applicants will be entitled to rejoinder as a matter of right if the product claims are deemed patentable. Applicants intend to request such rejoinder in the event the Office retains the restriction requirement and the product claims are eventually deemed patentable.

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[1] MPEP § 803 (emphasis added).

Moreover, applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter.

The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 19-1345.

Respectfully submitted,

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